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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/825,423	04/03/2001	Patricia C. Weber	ID01152	2057

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SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER	
ODELL, LINDSAY T	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 02/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/825,423	WEBER et al.	
	Examiner	Art Unit	
	Lindsay Odell	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Application Status

1. Claims 1-20 are pending.

Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5 and 7-17, drawn to a polypeptide fragment of an HCV helicase, derived from subdomain I of the HCV NS3 helicase, classified in class 435, subclass 195.

II. Claims 1-2, 6, 8-10, and 16-17, drawn to a polypeptide fragment of an HCV helicase, derived from subdomain II of the HCV NS3 helicase, classified in class 435, subclass 195.

III. Claims 1-2, 10, and 16-17, drawn to drawn to a polypeptide fragment of an HCV helicase protein, derived from subdomain III of the HCV NS3 helicase protein, classified in class 435, subclass 195.

IV. Claims 18-19, drawn to a method for preparing a purified crystalline composition comprising a purified polypeptide fragment of an HCV helicase, derived from subdomain I of the HCV NS3 helicase, classified in class 435, subclass 195.

V. Claim 18, drawn to a method for preparing a purified crystalline composition comprising a purified polypeptide fragment of an HCV helicase, derived from subdomain II of the HCV NS3 helicase, classified in class 435, subclass 195.

VI. Claim 18, drawn to a method for preparing a purified crystalline composition comprising a purified polypeptide fragment of an HCV helicase, derived from subdomain III of the HCV NS3 helicase, classified in class 435, subclass 195.

VII. Claim 20, drawn to a method for identifying an inhibitor of an HCV helicase comprising contacting the compound to subdomain I of the HCV NS3 helicase, classified in class 435, subclass 7.1.

VIII. Claim 20, drawn to a method for identifying an inhibitor of an HCV helicase comprising contacting the compound to subdomain II of the HCV NS3 helicase, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

The polypeptides of Groups I-III are related by virtue of the fact that they are all comprised of linear, contiguous amino acids that fold into specific three-dimensional structures, each being an individual domain in the HCV NS3 helicase protein. Although the polypeptides are related, they are distinct inventions because they have different structural and functional features. The polypeptides of Group I contain NTP and Mg^{++} binding sites, the polypeptides of Group II have a nucleic acid binding site, and the polypeptides of Group III have an extensive helical structure. While the domains function together to produce a helicase activity, each domain has distinct structural and functional features that contribute to this activity. The polypeptides of Groups I-III have different amino acid sequences from each other. Polypeptides must be searched both in commercial amino acid sequence databases and in textual databases because isolated polypeptides are often disclosed without the benefit of sequence information,

although the amino acid sequence is inherently the same as the sequence claimed. Therefore, a different search in commercial amino acid sequence databases is required for the claims in each of Groups I-III. To search Groups I-III together would present a search burden on the Office because the searches in commercial amino acid sequence databases are not co-extensive. Thus, Groups I-III have been appropriately restricted from each other on the basis of being both independent or distinct, and presenting a search burden on the Office if they were to be searched together.

The methods of Groups IV-VI are related by virtue of the fact that they are all drawn to preparing a crystalline composition of polypeptide fragments of the HCV NS3 helicase protein. Although the methods are related, they are distinct inventions because the polypeptide fragments used in the methods of Groups IV-VI have distinct structural and functional features, as described above. A different search in commercial amino acid sequence databases is required for the claims in each of Groups IV-VI because the substrates have different amino acid sequences. To search Groups IV-VI together would present a search burden on the Office because the searches in commercial amino acid sequence databases are not co-extensive. Thus, Groups IV-VI have been appropriately restricted from each other on the basis of being both independent or distinct, and presenting a search burden on the Office if they were to be searched together.

The products of Group I are related to the methods of Group IV as products and process of use. The polypeptide fragments of Group I can be used as substrates in the method steps of Group IV. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptide fragments of Group I can be used in a materially different process of using those products; for example, the polypeptide fragments can be used in method of identifying an inhibitor of HCV helicase, which has different method steps than the methods of Group IV. In addition, a different key-word search of textual databases is required for the methods of Group IV than is required for products of Group I. Because these inventions are distinct for the reasons given above, and the searches are not co-extensive, restriction for examination purposes as indicated is proper. Groups I and IV are patentably distinct, and present a search burden on the Office if they were to be searched together.

The products of Group II are related to the methods of Group V as products and process of use. The polypeptide fragments of Group II can be used as substrates in the method steps of Group V. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptide fragments of Group II can be used in a materially different process of using those products; for example, the polypeptide fragments can be used in method of identifying an inhibitor of HCV helicase, which has different method steps than the methods of Group V. In addition, a different key-word search of textual databases is required for the methods of Group V than is required for products of Group II. Because these inventions are distinct for the reasons given above, and the searches are not co-extensive, restriction for examination purposes as indicated is proper.

Groups II and V are patentably distinct, and present a search burden on the Office if they were to be searched together.

The products of Group III are related to the methods of Group VI as products and process of use. The polypeptide fragments of Group III can be used as substrates in the method steps of Group VI. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptide fragments of Group III can be used in a materially different process of using those products; for example, the polypeptide fragments can be used in method of identifying an inhibitor of HCV helicase, which has different method steps than the methods of Group VI. In addition, a different key- word search of textual databases is required for the methods of Group VI than is required for products of Group III. Because these inventions are distinct for the reasons given above, and the searches are not co-extensive, restriction for examination purposes as indicated is proper. Groups III and VI are patentably distinct, and present a search burden on the Office if they were to be searched together.

The polypeptide fragments of Group I are related to the methods of Groups V and VI because the methods of Groups V and VI use polypeptide fragments of an HCV helicase. Although the polypeptides of Group I are related to the methods of Groups V and VI, they are distinct inventions because the method steps of Groups V and VI do not include the use of the polypeptide fragments of Group I. The methods of Groups V and VI use polypeptide fragments derived from subdomains II and III, respectively, of HCS NS3 helicase. In contrast, the

polypeptide fragments of Group I are derived from subdomain I of HCD NS3 helicase. The polypeptides of Group I are different in structure and function from the polypeptides used in the method steps of Groups V and VI, as previously described. The search of the polypeptides of Group I in commercial databases is not required for the method steps of Groups V and VI. Because these inventions are distinct for the reasons given above, and the search for Group I is not coextensive with the search for Groups V and VI, restriction for examination purposes as indicated is proper. Group I and Groups V and VI are patentably distinct, and present a search burden on the Office if they were to be searched together.

The polypeptide fragments of Group II are related to the methods of Groups IV and VI because the methods of Groups IV and VI use polypeptide fragments of an HCV helicase. Although the polypeptides of Group II are related to the methods of Groups IV and VI, they are distinct inventions because the method steps of Groups IV and VI do not include the use of the polypeptide fragments of Group II. The methods of Groups IV and VI use polypeptide fragments derived from subdomains I and III, respectively, of HCS NS3 helicase. In contrast, the polypeptide fragments of Group II are derived from subdomain II of HCD NS3 helicase. The polypeptides of Group II are different in structure and function from the polypeptides used in the method steps of Groups IV and VI, as previously described. The search of the polypeptides of Group II in commercial databases is not required for the method steps of Groups IV and VI. Because these inventions are distinct for the reasons given above, and the search for Group II is not coextensive with the search for Groups IV and VI, restriction for examination purposes as indicated is proper. Group II and Groups IV and VI are patentably distinct, and present a search burden on the Office if they were to be searched together.

The polypeptide fragments of Group III are related to the methods of Groups IV and V because the methods of Groups IV and V use polypeptide fragments of an HCV helicase. Although the polypeptides of Group III are related to the methods of Groups IV and V, they are distinct inventions because the method steps of Groups IV and V do not include the use of the polypeptide fragments of Group III. The methods of Groups IV and V use polypeptide fragments derived from subdomains I and II, respectively, of HCS NS3 helicase. In contrast, the polypeptide fragments of Group III are derived from subdomain III of HCD NS3 helicase. The polypeptides of Group III are different in structure and function from the polypeptides used in the method steps of Groups IV and V, as previously described. The search of the polypeptides of Group III in commercial databases is not required for the method steps of Groups IV and V. Because these inventions are distinct for the reasons given above, and the search for Group III is not coextensive with the search for Groups IV and V, restriction for examination purposes as indicated is proper. Group III and Groups IV and V are patentably distinct, and present a search burden on the Office if they were to be searched together.

The methods of Groups VII and VIII are related by virtue of the fact that involve identifying inhibitors by contacting them with polypeptide fragments of the HCV NS3 helicase protein. Although the methods are related, they are distinct inventions because the polypeptide fragments used in the methods of Groups VII and VIII have distinct structural and functional features, as described above. A different search in commercial amino acid sequence databases is required for the claims in Groups VII and VIII because the substrates have different amino acid sequences. To search Groups VII and VIII together would present a search burden on the Office because the searches are not co-extensive. Thus, Groups VII and VIII have been appropriately

restricted from each other on the basis of being both independent or distinct, and presenting a search burden on the Office if they were to be searched together.

The products of Group I are related to the methods of Group VII as products and process of use. The polypeptide fragments of Group I can be used as substrates in the method steps of Group VII. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptide fragments of Group I can be used in a materially different process of using those products; for example, the polypeptide fragments can be used in a method of crystallization. In addition, a different key-word search of textual databases is required for the methods of Group VII than is required for products of Group I. Because these inventions are distinct for the reasons given above, and the searches are not co-extensive, restriction for examination purposes as indicated is proper. Groups I and VII are patentably distinct, and present a search burden on the Office if they were to be searched together.

The products of Group II are related to the methods of Group VIII as products and process of use. The polypeptide fragments of Group II can be used as substrates in the method steps of Group VIII. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptide fragments of Group II can be used in a materially different process of using those products; for example,

the polypeptide fragments can be used in a method of crystallization. In addition, a different key-word search of textual databases is required for the methods of Group VIII than is required for products of Group II. Because these inventions are distinct for the reasons given above, and the searches are not co-extensive, restriction for examination purposes as indicated is proper. Groups II and VIII are patentably distinct, and present a search burden on the Office if they were to be searched together.

The polypeptide fragments of Group III are related to the methods of Groups VII and VIII because the methods of Groups VII and VIII use polypeptide fragments of an HCV helicase. Although the polypeptides of Group III are related to the methods of Groups VII and VIII, they are distinct inventions because the method steps of Groups VII and VIII do not include the use of the polypeptide fragments of Group III. The methods of Groups VII and VIII use polypeptide fragments derived from subdomains I and II, respectively, of HCS NS3 helicase. In contrast, the polypeptide fragments of Group III are derived from subdomain III of HCD NS3 helicase. The polypeptides of Group III are different in structure and function from the polypeptides used in the method steps of Groups VII and VIII, as previously described. The search of the polypeptides of Group III in commercial databases is not required for the method steps of Groups VII and VIII. Because these inventions are distinct for the reasons given above, and the search for Group III is not coextensive with the search for Groups VII and VIII, restriction for examination purposes as indicated is proper. Group III and Groups VII and VIII are patentably distinct, and present a search burden on the Office if they were to be searched together.

The polypeptide fragments of Group I are related to the methods of Group VIII because the methods of Group VIII use polypeptide fragments of an HCV helicase. Although the

polypeptides of Group I are related to the methods of Group VIII, they are distinct inventions because the method steps of Group VIII do not include the use of the polypeptide fragments of Group I. The methods of Group VIII use polypeptide fragments derived from subdomain II of HCS NS3 helicase. In contrast, the polypeptide fragments of Group I are derived from subdomain I of HCD NS3 helicase. The polypeptides of Group I are different in structure and function from the polypeptides used in the method steps of Group VIII, as previously described. The search of the polypeptides of Group I in commercial databases is not required for the method steps of Group VIII. Because these inventions are distinct for the reasons given above, and the search for Group I is not coextensive with the search for Group VIII, restriction for examination purposes as indicated is proper. Groups I and VIII are patentably distinct, and present a search burden on the Office if they were to be searched together.

The polypeptide fragments of Group II are related to the methods of Group VII because the methods of Group VII use polypeptide fragments of an HCV helicase. Although the polypeptides of Group II are related to the methods of Group VII, they are distinct inventions because the method steps of Group VII do not include the use of the polypeptide fragments of Group II. The methods of Group VII use polypeptide fragments derived from subdomain I of HCS NS3 helicase. In contrast, the polypeptide fragments of Group II are derived from subdomain II of HCD NS3 helicase. The polypeptides of Group II are different in structure and function from the polypeptides used in the method steps of Group VII, as previously described. The search of the polypeptides of Group II in commercial databases is not required for the method steps of Group VII. Because these inventions are distinct for the reasons given above, and the search for Group II is not coextensive with the search for Group VII, restriction for

examination purposes as indicated is proper. Groups II and VI are patentably distinct, and present a search burden on the Office if they were to be searched together.

The methods of each of Groups IV-VI are related to the methods of each of Groups VII and VIII because the methods use polypeptide fragments of an HCV helicase. Although the methods of each of Group IV-VI are related to the methods of each of Groups VII and VIII, they are distinct inventions because the method steps and substrates of each of Groups IV-VI are different from the method steps and substrates of each of Groups VII and VIII. For example, the methods of each of Groups IV-VI do not require the use of potential inhibitor compounds of HCV helicase, which are required in the method steps of each of Groups VII and VIII. Because each of Groups IV-VI are distinct from each of Groups VII and VIII for the reasons given above, and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Each of Groups IV-VI are patentably distinct from each of Groups VII and VIII, and it would present a search burden on the Office if they were to be searched together.

Notice of Possible Rejoinder

3. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to

final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

I n the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Election

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lindsay Odell whose telephone number is 571-272-3445. The examiner can normally be reached on M-F, 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LO
February 2, 2005

KATHLEEN KERR, PH.D.
PRIMARY EXAMINER